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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,848	04/09/2004	Lawrence V. Tannenbaum	СНРРМ 03-22 03	8673
OFFICE OF THE STAFF JUDGE ADVOCATE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND ATTN: MCMR-JA (MS. ELIZABETH ARWINE) 504 SCOTT STREET FORT DETRICK, MD 21702-5012			EXAMINER	
			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## **Advisory Action**

Application No.	Applicant(s)	
10/820,848	TANNENBAUM, LAWRENCE V.	
Examiner	Art Unit	
Jerry Lin	1631	

Before the Filing of an Appeal Brief -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 21 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. 🛛 The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires \_\_\_\_\_months from the mailing date of the final rejection. a) b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b), ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. 🔀 The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal: and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. 🛛 For purposes of appeal, the proposed amendment(s): a) 🖾 will not be entered, or b) 🗌 will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: <u>1-6,13,15,16 and 18-21</u>. Claim(s) withdrawn from consideration: 7-12,14 and 17. AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. M The request for reconsideration has been considered but does NOT place the application in condition for allowance because: 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 13. Other: \_\_\_\_.

Continuation of Notes 3 and 7:

Applicants' proposed After Final Amendments to the claims introduce substantive changes that raise issues that require further search and/or consideration and therefore will not be entered. For example, claims 1 and 18, were amended to include the limitation of comparing results from rodents from a contaminated site and results from rodents from a reference site. This new limitation would require further consideration and/or search.

## Continuation of Note 11:

Rejection made under 35 U.S.C. §112, 1st paragraph, scope of enablement

Applicants replied to this rejection stating that rodents are a well-known model to estimate health effects and the data from rodents may be extrapolated for other animals. The Examiner partially agrees. While rodents are often used models to study health effects, it is also well known that the rodent model may not be accurately extrapolated to other animals. For example, clinical trials are conducts after animal studies because animal models do not accurately predict how humans would react to the same study. In addition, Phillips et al., state that while the rodent is a well-known model, they acknowledge that is it not necessarily an accurate model for all animals. Applicants also raise the example that if a site does not have any effect on a rodent it can be reasoned that the site is not affecting other animals. The Examiner disagrees. For example, amphibians, such as frogs, are often more sensitive to environmental changes than rodents because of their semi-preamble skin. Containments that do not effect rodents may readily effect amphibians.

Rejection made under 35 U.S.C. §112, 1st paragraph, new matter.

The Applicants have responded to this rejection by citing paragraph 0051 in their specification for support. The Examiner agrees, and this rejection is withdrawn.

Rejections made under 35 U.S.C.102 and 103

Applicants have responded to these rejections by stating that the references do not teach the claims as amended. Because the after final amendments were not entered, these rejections are maintained for reasons of record.

## **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majorie A. Moran can be reached at (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D. PRIMARY EXAMINER